K131161
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SEP 17 2013

Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address:	CIVCO Medical Instruments Co., Inc. d/b/a CIVCO Medical Solutions 102 First Street South Kalona, Iowa 52247
Contact Person:	Amanda Stahle, Regulatory Affairs Specialist Telephone: 319-248-6628, Fax: 877-218-0324 amanda.stahle@civco.com
Date Summary Prepared:	April 22, 2013
Trade Names:	EX3 Stepper™, Classic Stepper, Multi-Purpose Workstation™ Stepper; Micro-Touch™, Micro-Touch™ LP, Multi-Purpose Workstation™, Multi-Purpose Workstation™ LP; Disposable Template Grid (These devices are marketed as part of the AccuCARE™ product line)
Common Names:	Stepping Unit Stabilizer Disposable Template Grid
Classification Names:	Transducer, Ultrasonic, Diagnostic System, Applicator, Radionuclide, Manual System, Applicator, Radionuclide, Remote-controlled
Classification Numbers:	Class II under 21 CFR 892.1570 Class I under 21 CFR 892.5650 Class II under 21 CFR 892.5700
Review Panels:	Radiology
Product Codes:	ITX, IWJ, & JAQ

B. Predicate Devices

The subject devices are substantially equivalent to the predicate devices included in the following 510(k)s:

Predicate Devices	Mfg.
K972672: Brachystepper Stepping Unit, Brachystand Support and Manual Adjustment Accessory *Note: The Brachystepper Needle Guide Template component in this 510(k) is not being used as a predicate.*	Barzell-Whitmore Maroon Bells, Inc. (acquired by CIVCO Medical Instruments Co., Inc.)

Predicate Devices	Mfg.
K981873: Brachystepper™ Disposable Template Grid	Barzell-Whitmore Maroon Bells, Inc. (acquired by CIVCO Medical Instruments Co., Inc.)

The subject devices, with the exception of the EX3 Stepper, have been marketed for many years under K972672 and K981873. The purpose of this 510(k) is to modify the intended use of these devices to include cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. These additional applications fall within the indications for use and the literature demonstrates that these devices have been safely and effectively used for many years in these applications. These changes do not raise new issues of safety and effectiveness because the system continues to be used for positioning in males with suspected or diagnosed prostate cancer. These changes do not impact or modify the therapy and CIVCO did not modify the design of these devices to enable use in these additional applications.

The second purpose of this 510(k) is to provide a premarket notification for the EX3 Stepper. The EX3 Stepper is similar to the predicate in that it holds an ultrasound imaging probe and facilitates manual linear and rotational positioning of the probe. The EX3 Stepper differs from the predicate in that it offers continuous (free) longitudinal movement and contains encoder components that are powered via a USB-hub. Firmware in the encoders report position and this position is read by treatment planning software marketed by other companies. This position reporting function has been added to the EX3 intended use. Verification and validation testing confirmed that these changes in design do not raise new questions of safety and effectiveness.

C. Device Description

Stepping Unit

The Stepping Unit holds an ultrasound imaging probe and facilitates manual linear and rotational positioning of the probe. The Stepping Unit consists of a Cradle designed to hold a specific ultrasound probe and a Carriage that moves longitudinally along the Stepping Unit. A Grid Platform connected at one end of the Stepper provides support for the Disposable Template Grid. The Stepping Unit connects to the Stabilizer.

Stabilizer

The Stabilizer provides a base for the Stepping Unit and offers fixation and support during insertion and final placement of the ultrasound imaging probe. On certain models, a fine tune mechanism is used to micro-adjust the probe or instrument to the ideal orientation. The Stabilizer mounts to an operating room table or is supported by a floor stand.

Disposable Template Grid

The Disposable Template Grid is a single-use, sterile grid that consists of rows and columns of holes (channels) spaced 5mm apart. These channels are labeled and provide placement of needles in predefined areas of the prostate.

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The following part numbers are included in this 510(k):

Common Name	Trade Name	Part No.	Device Description
Stepping Unit	EX3 Stepper™	609-004	EX3 Stepper for use with Best Sonalis transducers
		612-228	EX3 Stepper for use with Acuson ER7B transducers
		614-119	EX3 Stepper for use with Aloka UST-672-5/7.5 transducers
		620-119	EX3 Stepper for use with B-K Medical 8658 (8558), 8848 transducers
		642-443	EX3 Stepper for use with GE Healthcare ERB transducers
		644-081	EX3 Stepper for use with Hitachi EUP-U533 transducers
		676-177	EX3 Stepper for use with Siemens Endo P-II transducers
		683-003	EX3 Stepper for use with Terason 8B4S transducers
	Classic Stepper	614-092	Classic Stepper for use with Aloka UST-672-5/7.5 transducers
		644-064	Classic Stepper for use with Hitachi EUP-U533 transducers
		612-225	Classic Stepper for use with Acuson ER7B transducers
		642-316	Classic Stepper for use with GE Healthcare ERB transducers
		620-089	Classic Stepper for use with B-K Medical 8658 (8558) transducers
		676-114	Classic Stepper for use with Siemens Endo-P II transducers
		609-001	Classic Stepper for use with Best Sonalis transducers
	Multi-Purpose Workstation™ Stepper	614-098	Multi-Purpose Workstation Stepper for use with Aloka UST-672-5/7.5
		642-334	Multi-Purpose Workstation Stepper for use with GE Healthcare ERB
		644-066	Multi-Purpose Workstation Stepper for use with Hitachi EUP-U533
		676-121	Multi-Purpose Workstation Stepper for use with Siemens Endo-P II
		620-094	Multi-Purpose Workstation Stepper for use with B-K Medical 8658 (8558), 8808
		620-113	Multi-Purpose Workstation Stepper for use with BK Medical 8808e, 8818
		620-117	Multi-Purpose Workstation Stepper for use with BK Medical 8848
Stabilizer	Micro-Touch™	610-911	Micro-Touch (Dual-Sided Table Mount)
		610-911S	Micro-Touch Transportation Stand

	Micro-Touch™ LP	610-912	Micro-Touch LP (Single-Sided Table Mount-right side)
		610-912S	Micro-Touch Transportation Stand
		610-913	Micro-Touch LP (Single-Sided Table Mount-left side)
		610-913S	Micro-Touch Transportation Stand
	Multi-Purpose Workstation™	610-974	Multi-Purpose Workstation with adjustable floor stand
	Multi-Purpose Workstation™ LP	610-975	Multi-Purpose Workstation LP with rail mount
Disposable Template Grid	Disposable Template Grid	610-905	Sterile 17GA Grid for use with AccuCARE Positioning and Stabilizing equipment
		610-906	Sterile 18GA Grid for use with AccuCARE Positioning and Stabilizing equipment
		610-915	Sterile 17GA Grid for use with B-K Medical UA-1084 Stepper
		610-916	Sterile 18GA Grid for use with B-K Medical UA-1084 Stepper

D. Indications for Use

This device is indicated for use in adult males with known or suspected prostate cancer.

E. Intended Use

System Intended Use:
Intended for use in ultrasonic procedures related to brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Component-specific Intended Uses:
Stepping Unit (Multi-Purpose Workstation Stepper, Classic Stepper): Holding and manipulating ultrasound imaging probes during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement procedures (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Stepping Unit (EX3 Stepper): Holding and manipulating ultrasound imaging probes, and reporting position, during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement procedures (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Stabilizer: Provides fixation, support and manipulation of transrectal ultrasound imaging probes during insertion and final placement.

Disposable Template Grid: Accepting and guiding needles up to 1.3 mm (18 gauge) in diameter and providing coordinates as an aid to needle loading and positioning during radioactive seed implantation, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement.

F. Technological Characteristics

Stepping Unit

Both the subject and predicate Stepping Units are designed to hold and manipulate ultrasound imaging probes during prostate procedures and enable manual linear and rotational positioning of the probe. The subject and predicate Stepping Units consist of a Cradle designed to hold and rotate an ultrasound probe, a Carriage that moves longitudinally along the Stepping Unit, and a Grid Platform connected at one end of the Stepper to attach the Disposable Template Grid. The proposed EX3 Stepper differs from the predicate in that it offers continuous (free) longitudinal movement of the Carriage and contains encoder components that are powered via a USB-hub. Firmware in the encoders report position and this position is read by treatment planning software marketed by other companies.

Stabilizer

Both the subject and predicate Stabilizers are designed to serve as a base for the Stepping Unit. The subject and predicate Stabilizers offer fixation and support during insertion and final placement of the ultrasound imaging probe. Whereas the predicate device only mounted on a floor stand, several of the subject Stabilizers can be mounted to an operating table. The fine tune adjustment mechanism on the predicate device is incorporated in the Micro-Touch Stabilizers, but not the Multi-Purpose Workstation Stabilizers.

Disposable Template Grid

Both the subject and predicate Disposable Template Grids are single-use, sterile grids that consist of rows and columns of holes (channels) spaced 5mm apart. These channels are labeled and provide placement of needles in predefined areas of the prostate. The subject device is sterilized via EtO gas, whereas the predicate device was sterilized by gamma irradiation. Also, the subject device is made of ABS while the predicate device was constructed from polycarbonate. The subject device is labeled with a 3 year expiration date.

G. Literature Review , Non-Clinical Performance Testing, and Conclusions

A literature review was conducted to support the modification of the intended use to include cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. The literature demonstrates that these devices have been safely and effectively used in cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. No design changes were made to enable use of the devices in these additional applications.

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Additionally, non-clinical performance testing was conducted on the EX3 Stepper including verification testing on the following characteristics:

- Stepping Unit is able to provide continuous (free) longitudinal movement
- Encoders correctly report longitudinal and rotational motion of Stepping Unit
- Stepping Unit meets electrical safety requirements of IEC 60601-1 and IEC 60601-1-1

Validation was also conducted to confirm the device remains safe and effective for its intended use and included testing with treatment planning software.

All testing confirmed that the EX3 Stepper is substantially equivalent to the predicate device in regards to safety and effectiveness and the new design features have not diminished the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

CIVCO Medical Instruments Co., Inc.
d/b/a CIVCO Medical Solutions
% Ms. Amanda Stahle
Regulatory Affairs Specialist
102 First Street South
KALONA IA 52247

Re: K131161
Trade/Device Name: Ex3 Stepper™, Classic Stepper, Multi-Purpose Workstation™ Stepper; Micro-Touch™, Micro-Touch™ LP, Multi-Purpose Workstation™, Multi-Purpose Workstation™ LP; and Disposable Template Grid
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX, IWJ, JAQ
Dated: August 28, 2013
Received: August 29, 2013

Dear Ms. Stahle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

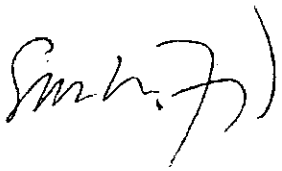
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131161

Device Name: Stepping Unit
Stabilizer
Disposable Template Grid

Indications for Use: This device is indicated for use in adult males with known or suspected prostate cancer.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131161